Memo of Meeting

Date: April 11, 2002

Representing Eurotherm, Inc.:

Jim Overturf, Vice President, Marketing
Christopher J. King, Regional Sales Manager
Karen Rigby, Business Product Manager, Data Management

Representing FDA:

Randall Woods, Consumer Safety Officer, (detailed to Office of Enforcement from) Center For Drug Evaluation and Research
Dave Doleski, Biologist, Center Biologics Evaluation and Research
Scott MacIntire, Director, Division of Compliance Information and Quality Assurance, Office of Enforcement
Tom Chin, Consumer Safety Officer, Office of Enforcement
Paul J. Motise, Consumer Safety Officer, Office of Enforcement

The meeting was held at the request of the Eurotherm representatives, to discuss their process automation data management products in the context of 21 CFR Part 11. The firm promotes its products as having been designed with part 11 requirements in mind. At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products or services that enable people to comply with FDA regulations. We advised that the meeting would be an information exchange and that our comments should not be taken as formal FDA positions.

The Eurotherm representatives explained that their 35 year old company is based in the United Kingdom and produces a line of process recording and electronic data acquisition systems, with less than half of it's business involved with sales to U.S. companies. A small percentage of their U.S. customers produce FDA regulated articles. However, the representatives explained that those industries have asked that the Eurotherm products include technical features required by part 11.

During the meeting the Eurotherm representatives demonstrated one of their data loggers and its electronic recordkeeping functions. The data logger has a touch screen color display and can take standard electrical inputs (e.g., 4 to 20 milliamp) to record such process events as temperature, pressure, and flow. The system is configurable and information in the form of electronic records is stored in flash memory from where it can be transferred to a network or external standard computer recording media.

The system draws the time from a network time server.

Operators are identified by electronic signatures based on identification codes in combination with passwords. The system can be configured to accept up to nine characters, but the password cannot be the same string of characters as the identification code. Security settings can be set by a system administrator and customized by individual permissions. Configurable settings include the number of allowable password retries before log-on rejections. Settings changed by the system administrator are recorded in an audit trail.

We commented that although part 11 does not specify a minimum password length, we suggested that the firm ship the units to FDA regulated customers with password defaults set to the higher security, maximum string length. We commented that in our opinion using a password that's only a single character long is not a secure practice, and that we were unaware of any mainstream standards or documents that advocated using that short a password.

Audit trailing covers configuration changes, and process actions. Audit trailing can be turned off by the system administrator and by default audit trailing is set to inactive. Audit trails are embedded in the trailed electronic record and include the date and time of the event, the nature of the event (record creation and modification), and the operator's identification. The Eurotherm representatives explained that the system does not permit records to be manually deleted. When the unit's flash memory is full, or upon a user entered command, records can be moved to external storage media or a network where audit trailing attendant to those external system (not those of Eurotherm) could be brought into play to record deletions. We suggested that the firm set the default audit trail to active, at least for FDA regulated customers.

Regarding electronic copies of the electronic records, the file format is such that the firm's proprietary PC based software is needed, although the messaging files, including audit trails and configuration files can be exported to MS Excel spreadsheet format.

During the meeting we discussed the firm's validation efforts. The representatives said they would welcome customer audits of their software development activities. The firm will also provide software functional specifications and test scripts upon request.

The representatives gave us several brochures describing their systems. We asked if the publications contained any material they viewed as trade secret, confidential, or otherwise non-disclosable to the public. They said no.

The meeting lasted about two hours.

cc:
FDA Attendees
HFA-224
Part 11 Guidance Dockets

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P. Motise 05/10/02